

PALENT/DOCKET NO. PC22004B

Appl. No. 10/761,636

Filing Date: January 21, 2004

Reply to Office action of February 8, 2006

REMARKS/ARGUMENTS

Pending claims are 1, 3, 4, 6-8 and 10-19. The claims are allowed with no amendments are 1, 3, 4, 7, 8 and 11. The Examiner has suggested the following claims may be allowed with amendments claims 6, 10, and 12. Suggested amendments appear in the claim listing above. The Examiner has suggested the following claims be rejected, and Applicant provides amendments and arguments as to why pending claims 13 - 19, should be allowed.

Claim 10 was objected to because of informalities and the amendments here should put the claims into condition for allowance. Claim 10 replace ~~either~~ with ether.

Claim 6 and 12 were rejected to because of informalities and the amendments here should put the claims into condition for allowance. Claim 6 replaced the parenthesis with commas. Claim 12, remove the parenthesis from item e, "(e) BHT { at less than 0.1% w/v } " this should now read "(e) BHT at less than 0.1% w/v." Item e should now be clear.

Claim 19 had two rejections, the basis for on rejection should be resolved applicant has replaced "of" with "or". "A kit useful in the treatment of or prophylaxis of a ..." Claim 19 also is rejected because of Examiner's concerns with it the invention in fact not acting as a prophylaxis.

Claims 13-19 were rejected because of the breadth of the claims, the Examiner asserting the claims describe an invention that does not work as described. That is the Examiner has suggested the application and prior art do not suggest that the described invention can both treat and prevent parasitic infections. Applicant provides arguments and information to prove the invention works exactly as claimed. In fact Applicant believes the Examiners comments provide yet additional proof of the outstanding nature of the invention. The invention in fact can be used to both treat and prevent these afflictions in animals. Applicant received market approval from the FDA, The CVM (The Center of Vet. Medicine) to both treat and prevent parasitic infections with selamectin.

Applicant provides quotes from the Pfizer web site, plus quotes from the label to prove selamectin both treats and controls both flea, heartworm, and has amended the claim to conform with the label for the treatment of various worms.

First to quote from the website.... <http://www.revolution4cats.com> Then click the link that says, "click here" to learn more about Revolution.

Treat prevent and control various parasites. **Q: What is Revolution® (selamectin)?**

A: Revolution is the first-ever FDA-approved, topically applied medication for cats that:

- Kills adult fleas (*Ctenocephalides felis*) and prevents flea eggs from hatching.
- Prevents heartworm disease caused by *Dirofilaria immitis*.
- Treats and controls ear mites (*Otodectes cynotis*).

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- Treats and controls roundworms (*Toxocara cati*) and hookworms (*Ancylostoma tubaeforme*).

Q: How does Revolution® (selamectin) work?

A: Revolution enters the bloodstream through the skin. Concentrations of Revolution in the blood and tissues prevent heartworm disease and prevent and treat roundworm and hookworm infections. Revolution selectively redistributes from the blood to the skin and other tissues, where it provides protection against fleas, flea eggs, and ear mites.

The Examiner states that according to Bishop et al., Veterinary Parasitology, 91, pp. 163-176, 2000, specifically page 174, first paragraph). As such, prophylaxis against fleas, heartworms, and tapeworms is not recognized in the art." And later the Examiner states he "acknowledges the probability and predictability that selamectin and praziquantel would have efficacy in treatment, however the art is silent with regard to the predictability of the formulation have preventative efficacy as asserted for fleas, heartworm and tapeworm."

Applicant replies that the US Federal agency that is responsible for evaluation those claims have in fact made that evaluation and approved the use of the drug for both prevention and treatment of these afflictions.

Applicant quotes from the label as follows:

What is Revolution?

Revolution is a topical parasiticide that is applied to the skin of dogs six weeks of age and older and cats eight weeks of age and older to kill adult fleas and prevent flea eggs from hatching, prevent heartworm disease and protect your pet against other parasites (see below).

Why has my veterinarian prescribed Revolution?

Revolution has been prescribed by your veterinarian to treat, prevent and/or control the following parasites in your dog or cat:

Dog Parasites:

- Control and prevention of flea infestation (*Ctenocephalides felis*)
- Prevention of heartworm disease (*Dirofilaria immitis*)
- Treatment and control of ear mite infestation (*Otodectes cynotis*)
- Treatment and control of sarcoptic mange (*Sarcoptes scabiei*)
- Control of the American Dog Tick (*Dermacentor variabilis*)

Cat Parasites:

- Control and prevention of flea infestation (*Ctenocephalides felis*)
- Prevention of heartworm disease (*Dirofilaria immitis*)
- Treatment and control of ear mite infestation (*Otodectes cynotis*)
- Treatment and control of intestinal worms
 - Roundworm (*Toxocara cati*)
 - Hookworm (*Ancylostoma tubaeforme*)

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Concerning fleas:**Dogs:**

Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. Revolution also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick infestations due to *Dermacentor variabilis*.

Cats:

Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. Revolution is also indicated for the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

Concerning heartworms:**Heartworm Prevention in Dogs and Cats**

For the prevention of heartworm disease, Revolution must be administered on a monthly basis. Revolution may be administered year-round or at least within one month after the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of Revolution and resumption of monthly dosing will minimize the opportunity for the development of adult heartworms. When replacing another heartworm preventive product in a heartworm disease prevention program, the first dose of Revolution must be given within a month of the last dose of the former medication.

Selamectin, the active ingredient in Revolution, is a macrocyclic lactone compound. These compounds effectively prevent the development of adult heartworms when administered to dogs and cats within one month of exposure to infective (L3) *Dirofilaria immitis* larvae. Efficacy of macrocyclic lactones decreases below 100% in dogs, however, if first administered >2 months after exposure to infective larvae. Thus, in heartworm endemic regions, delaying initiation of heartworm prevention using Revolution beyond 2 months of first exposure to infective larvae (e.g., starting puppies and kittens at >8 weeks of age), or gaps of >2 months in the administration of Revolution during periods of heartworm transmission, increases the risk of the animal acquiring heartworms. Animals with unknown heartworm history that test negative for heartworms prior to the initiation of Revolution may be harboring pre-patent infections at the time Revolution was started. Testing such animals 3-4 months after initiation of Revolution would be necessary to confirm their negative heartworm status.

At the discretion of the veterinarian, cats ≥6 months of age may be tested to determine the presence of existing heartworm infections before beginning treatment with Revolution. Cats already infected with adult heartworms can safely be given Revolution monthly to prevent further infections.

Concerning tapeworms: Applicant has adopted the Examiner's suggestion to refer to the treatment rather than the prevention of tapeworms.

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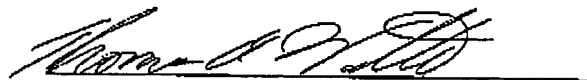
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Conclusion

Given the amendments and comments above, applicant believes claims 1, 3, 4, 6-8 and 10-19, are now in condition for allowance.

Respectfully submitted,



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Client Information About REVOLUTION® (selamectin) Revolution (pronounced "Rev-o-lution") Generic name: selamectin ("sel-a-mec-tin")

This summary contains important information about Revolution. You should read this information before you start using Revolution on your dog or cat and review it each time you give your pet a dose of Revolution. This sheet is provided only as a summary and does not take the place of the information on your veterinarian's advice. Please ask your veterinarian if you do not understand any of this information or if you want to know more about Revolution.

What is Revolution?

Revolution is a topical parasiticide that is applied to the skin of dogs six weeks of age and older and cats eight weeks of age and older to kill adult fleas and prevent flea eggs from hatching, prevent heartworm disease and protect your pet against ear mites (ear canal mites).

Why has my veterinarian prescribed Revolution?

Revolution has been prescribed by your veterinarian to treat, prevent and/or control the following parasites in your dog or cat:

- Fleas (Control and prevention of flea infestation (Ctenocephalides felis felis))
- Prevention of heartworm disease (Dirofilaria immitis)
- Prevention and control of ear mites (Otodectes cynotis)
- Prevention and control of sarcoptic mange (Sarcoptes scabiei)
- Control of the American Cystic Nod (Dermacentor variabilis)

Can I use Revolution on my dog or cat?

Revolution should not be used on dogs that are ill, debilitated or underweight animals. Dogs should be treated for heartworm disease prior to giving Revolution. If your dog has heartworm disease, your veterinarian can determine appropriate treatment. Dogs infected with adult heartworms can still be given Revolution. If your cat is ill or has a fever, your veterinarian may decide to wait until your cat is healthy before giving Revolution. Cats infected with adult heartworms can safely be given Revolution to prevent future infestation.

What dose of Revolution do I use on my dog or cat?

Revolution is given as a single application to the skin of your dog or cat based on your animal's body weight. You should not administer Revolution to dogs that weigh less than 5 weeks of age or cats younger than 5 weeks of age. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat.

What should I do if I do not give Revolution on time or miss a dose?

If you forget to apply a monthly dose of Revolution, immediately apply Revolution. If you forget to apply a monthly dose of Revolution, immediately apply Revolution. If you forget to apply a monthly dose of Revolution, immediately apply Revolution. If you forget to apply a monthly dose of Revolution, immediately apply Revolution. If you forget to apply a monthly dose of Revolution, immediately apply Revolution.

What if I administer more than the prescribed amount of Revolution to my dog or cat?

Contact your veterinarian if you administer more than the prescribed amount of Revolution. Know should Revolution be applied?



1. Remove the Revolution tube from its protective package.
2. Holding the tube upright, firmly press the cap down until you hear a "click" sound, which indicates that the cap has punctured the applicator seal. Remove the cap and check to see a small amount of liquid has come out of the tube.
3. Rub the tip of the tube along the skin at the base of the neck, in front of the shoulder blades, until the skin is visible.
4. Apply the tip of the Revolution tube directly to the skin. Squeeze the tube firmly 3-4 times until the liquid has been completely applied to the skin. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat.
5. Discard the tube properly. Do not reuse. Do not use on cats.

Do not use Revolution on the skin.

Do not apply to broken skin - Revolution contains alcohol.

Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats.

Can I give my pet a bath after applying Revolution?

Yes. Bathe your pet as soon as possible after applying Revolution. Bathe your pet as soon as possible after applying Revolution. Bathe your pet as soon as possible after applying Revolution. Bathe your pet as soon as possible after applying Revolution. Bathe your pet as soon as possible after applying Revolution.

When can I play with my pet following treatment with Revolution?

You should avoid contact with children who are on your pet's bed or play with your pet any time after the area on which Revolution was applied is dry. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat.

FEAS Carnivorous Animals



For best results, apply Revolution to the back of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat. Revolution is available in 3 sizes to match the weight of your dog or cat.

Immature stages of the flea (flea eggs) may be present in your pet's environment. Fleas, eggs, pupae, and adults are not killed by Revolution (including fleas and eggs). Fleas, eggs, pupae, and adults are not killed by Revolution (including fleas and eggs). Fleas, eggs, pupae, and adults are not killed by Revolution (including fleas and eggs). Fleas, eggs, pupae, and adults are not killed by Revolution (including fleas and eggs).

What are the possible side effects of Revolution?

Like all medicines, Revolution has some side effects. The most common side effects are: Itching, redness, and swelling. Itching, redness, and swelling. Itching, redness, and swelling. Itching, redness, and swelling. Itching, redness, and swelling.

What should I do if my dog or cat has a side effect?

Contact your veterinarian if your dog or cat has a side effect. Contact your veterinarian if your dog or cat has a side effect. Contact your veterinarian if your dog or cat has a side effect. Contact your veterinarian if your dog or cat has a side effect. Contact your veterinarian if your dog or cat has a side effect.

Can Revolution be given with other medicines?

Revolution can be given with other medicines. Revolution can be given with other medicines. Revolution can be given with other medicines. Revolution can be given with other medicines. Revolution can be given with other medicines.

How should I store Revolution?

Revolution should be stored in its original container. Revolution should be stored in its original container. Revolution should be stored in its original container. Revolution should be stored in its original container. Revolution should be stored in its original container.

What else should I know about Revolution?

Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats. Revolution is not for use on cats.

Revolution

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